



VA ResearchCurrents

VA to track veterans with ALS through National Registry

As part of its efforts to understand and treat a fatal neurological disorder that has been linked to Gulf War deployment, VA is creating a National Registry of Veterans with Amyotrophic Lateral Sclerosis (ALS.) The Registry, based at the Durham (N.C.) VA Medical Center, will identify and track the health status of veterans with ALS and help in recruiting veterans for clinical trials of new treatments.

In light of recent research by VA and the Department of Defense, VA's Office of Research and Development (ORD) forged plans to create the new registry, which is open to all veterans with ALS. ORD also restated its commitment to exploring all avenues to

advance understanding of possible connections between military service and ALS and increase protection for those in future deployments.

ALS, also known as Lou Gehrig's disease, kills the brain and spinal cord cells that control muscle movement, resulting in gradual muscle wasting and loss of movement. Only 20 percent of ALS patients live beyond five years. The incidence of ALS is about equal to that of multiple sclerosis, affecting as many as 30,000 Americans at a given time. The disease usually strikes those between ages 40 and 70. There is no cure as yet.

In preliminary study findings announced by VA in Dec. 2001, ALS

was nearly twice as prevalent among veterans who had been deployed to the Persian Gulf region in 1990 and 1991 than among those not deployed. The incidence was especially high among Air Force personnel who served in the conflict. They were 2.7 times more likely to develop ALS than non-deployed personnel.

The \$1.5 million study, funded by VA and the Department of Defense and involving other federal health agencies, has resulted in the first link between Persian Gulf service and a specific known disease. Other research on veterans of Desert Shield and Desert Storm has confirmed they are at higher risk for a mysterious cluster of symp-

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Update from the Cooperative Studies Program...

Survey shows high level of participant satisfaction with clinical trials

By Steven M. Berkowitz, PhD, *Assistant Director*

The VA Cooperative Studies Program (CSP) prides itself on conducting clinical trials that provide definitive empirical evidence to guide optimal healthcare for our veterans. We had always thought that our veterans appreciated the opportunity to participate; recently, we set out to empirically validate our impressions and ask our participants directly. Satisfaction surveys are frequently given to customers to determine consumer satisfaction with a product or service, as well as to learn more about the target audience. However, there is little mention in medical literature of a similar process being applied to evaluate participant satisfaction with research.

The Institute of Medicine has recommended, in fact, that research organizations begin surveying participants on their experience. This study is one of the first such efforts to occur, and represents CSP's commitment to ensure the highest possible satisfaction for the veterans who take part in our research.

With project coordination from "MAVERIC," the CSP center in Boston, CSP leadership collaborated on developing and implementing the survey. Each CSP Coordinating Center selected participating sites from ongoing CSP clinical trials. Each local IRB approved the survey, and each site

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distributed the survey to patients in those trials. Of 178 surveys distributed, 154 surveys were returned, and only one was returned blank. The response rate was approximately 86 percent.

The responses were quite positive. When asked "Overall, how do you feel about your participation in a VA Cooperative Study?", 97 percent of participants said either "positive" or "very positive" (with "neutral," "negative" or "very negative" as other options). The vast majority agreed they received good care and were treated with respect. About 70 percent of participants thought the study improved either their health or the medical care they received, regardless of the treatment arm to which they were assigned. Eighty-one percent of all participants were willing to participate in another study.

The full results of this effort will be submitted for scientific publication so we may encourage other investigators or sponsors to actively measure the satisfaction of research participants.

CSP plans to implement participant satisfaction assessment as a regular part of CSP studies. This will help ensure that we design studies relevant to veterans' healthcare; that we provide veterans maximal opportunity to participate; and that we conduct research that adheres to the highest ethical standards. ■

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103 S. Gay St., Rm. 517
Baltimore, MD 21202
(410) 962-1800, ext. 223
researchinfo@vard.org

Recent publications and presentations

Below is a sampling of recent publications by VA investigators. Due to space constraints, only VA authors and affiliations are noted. Notifications of upcoming publications and presentations can be faxed to (410) 962-0084 or e-mailed to researchinfo@vard.org.

"Cancer Chemoprevention Drug Targets." Koyamangalath Krishnan, MD; F. Abdel-Rahman, MD. **Mountain Home** (Tenn.) *Current Drug Targets*, Jan. 2003.

"Carotid Endarterectomy and Race: Do Clinical Indications and Patient Preferences Account for the Differences?" Eugene Z. Oddone, MD, MHSc; Ronnie D. Horner, PhD; Linda G. Alley, RN, PhD; Jeff Whittle, MD; Laura Kroupa, MD; John Taylor, MD. **Durham** (EZO, RDH), **Atlanta** (LGA), **Pittsburgh** (JW), St. Louis (LK), **Richmond**, Va. (JT). *Stroke*, Dec. 2002.

"Dissociation Between Conflict Detection and Error Monitoring in the Human Anterior Cingulate Cortex." Diane Swick, PhD; And U. Turken, PhD. **Martinez** (Calif.) *Proceedings of the National Academy of Sciences*, Dec. 10, 2002.

"Health Care Utilization Associated with PTSD and Personality Disorders." Serena Chu, PhD. **Houston**. Annual Meeting of the International Society for Traumatic Stress Studies, Nov. 2002.

"IGF-1 and IGFBP-3 Transport in the Rat Heart." Mary Boes, Brian L. Dake, Barbara A. Booth, PhD; Robert S. Bar, MD. **Iowa City**. *American Journal of Physiology: Endocrinology and Metabolism*, Jan. 2003.

"Influence of Prior Hyperbaric Oxygen Therapy in Complications Following Microvascular Reconstruction for Advanced Osteoradionecrosis." TJ Gal, Bevan Yueh, MD; Neal D. Futran, MD, DMD. **Seattle**. *Archives of Otolaryngology: Head and Neck Surgery*, Jan. 2003.

"Quality of Life Assessment Software For Computer-Inexperienced Older Adults: Multimedia Utility Elicitation for Activities of Daily Living." Mary K. Goldstein, MD; Alan M. Garber, MD, PhD. **Palo Alto**. *Proceedings of the American Medical Informatics Association*, 2002.

"Quality of Life with and without Aphasia." Katherine B. Ross, PhD; Robert T. Wertz, PhD. **Phoenix** (KBR) and **Nashville** (RTW). American Speech-Language-Hearing Association Convention, Nov. 2002.

"Racial and Ethnic Disparities in the Use of Health Services." Carol M. Ashton, MD, MPH; Paul Haidet, MD, MPH; Debora A. Paterniti, PhD; Tracie C. Collins, MD, MPH; Howard S. Gordon, MD; Kimberly O'Malley, PhD; Laura A. Petersen, MD, MPH; Maria E. Suarez-Almazor, MD, PhD; Nelda P. Wray, MD, MPH. **Houston**. *Journal of General Internal Medicine*, Feb. 2003.

"Safety and Efficacy of Sodium Ferric Gluconate Complex in Patients with Chronic Kidney Disease." Rajiv Agarwal, MD. **Indianapolis**. *American Journal of Kidney Disease*, Nov. 2002.

"U.S. Veterans' Experience with Rebetrone in a Non-Study Environment: Success or Failure?" Christopher Y. Kim, MD. **Charleston**. *American Journal of Gastroenterology*, Sept. 2002.

National Hotline Conference Call schedule:
http://vaww.va.gov/resdev/fr/call_calendar.cfm

San Diego-based AIDS researcher wins Middleton Award

Douglas D. Richman, MD, a virologist at the Veterans Affairs (VA) San Diego Healthcare System whose research on HIV and AIDS has helped guide treatment for millions of patients worldwide, will receive the 2002 Middleton Award, VA's highest honor for biomedical investigators.

Richman, director of the Research Center for AIDS and HIV Infection at the San Diego VA and the Center for AIDS Research at the University of California, San Diego, is noted for his studies of zidovudine, or azidothymidine (AZT), the first drug approved in the United States to treat HIV. Richman and colleagues established the effectiveness of the drug in clinical trials in the late 1980s. Later studies by Richman revealed the emergence of AZT-resistant strains of HIV. The appreciation of the importance of HIV drug resistance and his pioneering studies of combination

therapy led to the development in the 1990s of highly active antiretroviral therapy (HAART).

Today, Richman continues to play a major role in setting the national agenda for AIDS research and care. Recent research by Richman showed that more than three-quarters of HIV patients in the United States with a measurable viral load carry strains of the virus that are resistant to drug therapy. The study underscored the need for drug resistance testing, which helps identify which medications will be effective for a patient. Richman has also shown that HAART does not completely eradicate HIV, but leaves small reservoirs of HIV in immune cells—even when blood tests show no trace of the virus. Amid these findings, Richman is in the forefront of efforts to study neutralizing antibody to HIV, which may be of particular importance in the development of an AIDS vaccine.

Richman is the author of more than 460 articles in the medical literature and is co-editor of the textbook *Clinical Virology*. He has served on the editorial board of 15 journals and is editor-in-chief of *Topics in HIV Medicine and AIDS Therapy*. He has been an advisor to the Food and Drug Administration and the World Health Organization, and serves on the AIDS Vaccine Research Committee of the National Institutes of Health. Richman is also a member of the Executive Committee on HIV for VA's Quality Enhancement Research Initiative (QUERI).

The Middleton Award was established by VA in 1960 to honor William S. Middleton, MD, an educator and physician-scientist who served as VA's chief medical director from 1955 to 1963. The award is given each year to a senior VA investigator for major achievements in areas of prime importance to VA's research mission. ■

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toms known as Gulf War Illness, involving chronic fatigue, musculoskeletal problems, asthma, post-traumatic stress disorder, depression, memory loss and other problems. VA researchers on the Gulf War study recently completed identifying veterans for the final phase of the study and are exploring possible reasons for the higher rate of ALS among the deployed veterans, such as exposure to biological or chemical toxins.

The ALS Registry will be directed by the Epidemiologic Research and Information Center at the Durham VA Medical Center, with cooperation from the VA Medical Center in Lexington, Ky. Co-principal investigators are Eugene Oddone, MD, MHSc, and Ed Kasarskis, MD, PhD. Veterans of any era who have a diagnosis of ALS are eligible to enroll. They will complete an initial telephone interview, covering their health and military service, and will be interviewed twice yearly thereafter. Enrollees may be contacted regarding clinical trials and other studies related to ALS, but are under no obligation to participate.

Since 1994, VA, the Department of Defense and the Department of Health and Human Services have spent \$213 million on 224 research projects relating to the health effects of military deployment. VA plans to spend up to an additional \$20 million on this initiative by the end of fiscal 2004.

For more information about the ALS Registry, call 1-877-DIAL-ALS or e-mail norma003@acpub.duke.edu.

On the VA research website...

- VA's newest solicitation for research on the health effects of military deployment, see www.va.gov/resdev/fr/ProgramAnnouncementDeploymentHealthIssues.pdf.
- VA's updated policy directive on security in biomedical labs can be found at www.va.gov/resdev/directive/HAZMAT-Directive-revised1.doc.

New phone, fax numbers for ORD

Due to changes in location, VA's Office of Research and Development has new phone and fax numbers, as listed below. All numbers are area code 202.

Office of Research and Development

Tel: 254-0183 /0184;

Fax: 254-0460

Medical Research Service

Tel: 408-3600; Fax: 275-6100

Rehabilitation Research and Development Service

Tel: 254-0255; Fax: 254-0473

Health Services Research and Development Service

Tel: 254-0207 /0208; Fax: 254-0461

Cooperative Studies Program

Tel: 254-0272; Fax: 254-0471/0472.

National
VA Research Week:
April 20 – 26, 2003

Few disparities in VA heart care for mentally ill

There is little disparity between heart attack care at VA medical centers for those with and without a history of mental illness or substance abuse, according to a study in the February issue of *Health Services Research*. Previous research on mentally ill patients in non-VA health systems shows they receive poorer care than patients with no mental illness and have higher rates of mortality for several conditions, including heart attacks.

Laura A. Petersen, MD, MPH, of VA's Houston Center for Quality of Care and Utilization Studies and Baylor College of Medicine, and colleagues from Yale and Harvard analyzed the records of 4,340 patients who received care for heart attack at 81 VA hospitals in 1994 and 1995. Of these, about 20 percent had received a diagnosis of schizophrenia, depression or other mental illness, or been treated for substance abuse. Patients in both groups—excluding those with medical

contraindications—were equally likely to receive medications shown to increase survival after heart attack. Patients in both groups who received diagnostic angiography were equally likely to receive angioplasty or coronary artery bypass surgery.

On the other hand, there was a slightly lower rate of diagnostic angiography among the mentally ill, both during their initial hospital stay at VA and within 90 days of follow up, either at VA hospitals or private hospitals that accept Medicare. Also, while both groups had equal survival rates for 90 days after the heart attack, patients with mental illness may have been more likely to die within the year—although this finding did not reach statistical significance. Petersen said these findings are not surprising in light of previous research on the health outcomes of psychiatric patients, who may have increased socioeconomic burdens, fear of medical procedures, or other factors that interfere with their care. ■

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VA Research and Development Communications
Department of Veterans Affairs
103 S. Gay St., Rm. 517
Baltimore, MD 21202